IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **AJANTA PHARMA LIMITED,** **Defendant.**	**Civil Action No. _____**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint for Patent Infringement against Defendant Ajanta Pharma Limited ("Ajanta" or "Defendant"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 7,722,898 ("the '898 patent"), United States Patent No. 7,910,131 ("the '131 patent"), United States Patent No. 8,617,600 ("the '600 patent"), United States Patent No. 8,821,930 ("the '930 patent"), United States Patent No. 9,119,791 ("the '791 patent"), United States Patent No. 9,351,975 ("the '975 patent"), United States Patent No. 9,370,525 ("the '525 patent"), United States Patent No. 9,855,278 ("the '278 patent"), United States Patent No. 10,220,042 ("the '042 patent"), United States Patent No. 11,166,960 ("the '960 patent"), attached hereto as Exhibits A–J (collectively, "the patents in suit").

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

3. Upon information and belief, Defendant Ajanta Pharma Limited is a corporation operating and existing under the laws of India, with its principal place of business at Ajanta House, Charkop, Kandivli West, Mumbai-400 067, Maharashtra, India.

4. According to Defendant's website, "Ajanta Pharma is a specialty pharmaceutical company engaged in development, manufacture and marketing of quality finished dosages in domestic and international markets" with over 7,000 employees operating in more than 30 countries across 4 continents. Ajanta Website, http://www.ajantapharma.com/index.aspx (accessed October 5, 2022).

5. Ajanta's Annual Report 2021-2022 states that it experienced "9% growth in the US generics" for FY 2022. Ajanta's Annual Report 2021-2022 at 19, http://www.ajantapharma.com/AdminData/AnnualReports/Ajanta-Annual-Report-FY22.pdf (accessed October 5, 2022). Ajanta's Annual Report 2021-2022 further states that "we launched 3 new products and filed 8 ANDAS. We received 2 final and 1 tentative approval. There are 20 ANDAs awaiting approval from US FDA." Ajanta's Annual Report 2021-2022 at 10, http://www.ajantapharma.com/AdminData/AnnualReports/Ajanta-Annual-Report-FY22.pdf (accessed October 5, 2022).

6. Upon information and belief, Ajanta is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the state of Delaware, and importing generic pharmaceutical products into the United States, including throughout the state of Delaware; (ii) in concert with and/or

through its various subsidiaries or representatives, the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the state of Delaware; and (iii) in concert with and/or through its various subsidiaries or representatives, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the state of Delaware.

7. Upon information and belief, Ajanta filed ANDA No. 217659 ("the Ajanta ANDA") with FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic oxcarbazepine extended-release tablets, containing 150 mg, 300 mg, and 600 mg of oxcarbazepine ("the Ajanta Products").

8. Upon information and belief, Ajanta develops, manufactures, imports, markets, distributes, and/or sells pharmaceutical products—including generic drug products (e.g., Sildenafil Tablets (25 mg, 50 mg, and 100 mg), Risperidone Tablet (0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg), Clomipramine Hydrochloride Capsules (25 mg, 50 mg, and 75 mg), Aripiprazole Tablet (2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg), and Tadalafil Tablet (2.5 mg, 5 mg, 10 mg, 20 mg)) that will be manufactured and sold pursuant to an ANDA—throughout the United States, including throughout the state of Delaware.

9. Upon information and belief, Ajanta and/or its affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which Ajanta is the named ANDA applicant. Upon information and belief, Defendant directly and indirectly derives substantial revenue from the sales of such generic pharmaceutical products.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Defendant under Fed. R. Civ. P. 4, including, without limitation, Fed. R. Civ. P. 4(k)(2).

12. Upon information and belief, Defendant has purposefully availed itself of the privilege of doing business in the state of Delaware by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the state of Delaware. For example, upon information and belief, Defendant states on its website that it is "gradually building a meaningful presence in the US market with select product portfolio, which include complex technology products to get the competitive advantage in the marketplace. We expect US market to be our key growth driver in the coming years." Ajanta Website, http://www.ajantapharma.com/overview.html (accessed October 5, 2022). Defendant further states on its website that "[o]ur products are already available on the shelf in US through our subsidiary . . . ." Ajanta Website, http://www.ajantapharma.com/generics.html (accessed October 5, 2022). In addition, Defendant's website indicates that as of March 2022, Defendant had 39 commercialized ANDA approvals with an additional 20 ANDA products awaiting US FDA approval. Ajanta Website, http://www.ajantapharma.com/generics.html (accessed October 5, 2022).

13. This Court has personal jurisdiction over Ajanta at least because, upon information and belief: (i) Ajanta has purposefully directed its activities (and the activities of its affiliates) at residents and corporate entities within the state of Delaware; (ii) the claims set forth herein against Ajanta arise out of or relate to those activities; (iii) Ajanta's contacts with the state of Delaware (direct and indirect) are continuous and systematic; and (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Ajanta.

14. In addition, this Court has personal jurisdiction over Ajanta at least because, upon information and belief, Defendant regularly engages in patent litigation in this Judicial District and has previously submitted to the jurisdiction of this Court, has availed itself of Delaware's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.[1]

15. Upon information and belief, Ajanta's tortious acts of (i) preparing and filing ANDA No. 217659 with paragraph IV certification to the patents in suit for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the Ajanta Products before the expiration of the patents in suit, and (ii) directed notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of the Ajanta Products by Defendant before the expiration of the patents in suit throughout the United States, including this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Ajanta should reasonably anticipate being sued in Delaware.

16. This Court has personal jurisdiction over Defendant at least because, upon information and belief, if ANDA No. 217659 is approved, the Ajanta Products will be marketed and distributed by or at the direction and under the control of Ajanta in the state of Delaware,

[1] This Court also has personal jurisdiction over Defendant because Ajanta previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by consenting to this Court's jurisdiction and asserting claims and/or counterclaims in this Court. *See, e.g.*, *Otsuka Pharma Co. Ltd. v. Ajanta Pharma Ltd.*, Civil Action No. 19-1939-LPS (D. Del.) (Ajanta did not contest jurisdiction) and *Amgen Inc. v. Ajanta Pharma Limited, et. al.*, Civil Action No. 16-899-GMS (D. Del.) (Ajanta did not contest jurisdiction and filed a counterclaim).

prescribed by physicians practicing in the state of Delaware, dispensed by pharmacies located within the state of Delaware, and used by patients in the state of Delaware.

17. Venue is proper for Ajanta under 28 U.S.C. §§ 1391 or 1400(b) because, *inter alia*, Ajanta is subject to personal jurisdiction in this Judicial District, as set forth above, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth above, and/or continuously transacts business in this Judicial District, as set forth above.

18. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b), 1391(c), and § 1400(b).

FACTS AS TO ALL COUNTS

19. Supernus owns New Drug Application ("NDA") No. 202810, which was approved by FDA for the manufacture and sale of oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg, which Supernus markets under the name Oxtellar XR®.

20. Oxtellar XR® is an antiepileptic drug indicated for: (i) monotherapy or adjunctive therapy in the treatment of partial seizures in adults; and (ii) monotherapy or adjunctive therapy in the treatment of partial seizures in children 6 to 17 years of age.

21. The '898 patent, entitled "Modified-Release Preparations Containing Oxcarbazepine and Derivatives Thereof," was duly and legally issued by the United States Patent and Trademark Office on May 25, 2010, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '898 patent.

22. The '131 patent, entitled "Method of Treating Seizures Using Modified Release Formulations of Oxcarbazepine," was duly and legally issued by the United States Patent and Trademark Office on March 22, 2011, to Supernus upon assignment from inventors Padmanabh

P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '131 patent.

23. The '600 patent, entitled "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof," was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '600 patent.

24. The '930 patent, entitled "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof," was duly and legally issued by the United States Patent and Trademark Office on September 2, 2014, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '930 patent.

25. The '791 patent, entitled "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof," was duly and legally issued by the United States Patent and Trademark Office on September 1, 2015, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '791 patent.

26. The '975 patent, entitled "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof," was duly and legally issued by the United States Patent and Trademark Office on May 31, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '975 patent.

27. The ’525 patent, entitled “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof,” was duly and legally issued by the United States Patent and Trademark Office on June 21, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’525 patent.

28. The ’278 patent, entitled “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof,” was duly and legally issued by the United States Patent and Trademark Office on January 2, 2018, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’278 patent.

29. The ’042 patent, entitled “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof,” was duly and legally issued by the United States Patent and Trademark Office on March 5, 2019, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’042 patent.

30. The ’960 patent, entitled “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof,” was duly and legally issued by the United States Patent and Trademark Office on November 9, 2021, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’960 patent.

31. Pursuant to 21 U.S.C. § 355(b)(1), the patents in suit are listed in FDA’s publication titled, “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known

as the "Orange Book") in connection with Oxtellar XR®. Supernus submitted the patents in suit to FDA to be listed in the Orange Book for NDA No. 202810.

32. Upon information and belief, Defendant prepared and filed the Ajanta ANDA with FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products and included a "paragraph IV" certification seeking approval before the expiration of patents in suit.

33. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

34. On or about September 19, 2022, Ajanta sent a letter purportedly pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. §§ 314.94, 314.95 regarding the Ajanta Products and the '898 patent, the '131 patent, the '600 patent, the '930 patent, the '791 patent, the '975 patent, the '525 patent, the '278 patent, the '042 patent, and the '960 patent (the "September 19 Notice Letter").

35. The September 19 Notice Letter contends that the Ajanta Products do not infringe independent claim 1 of each of the patents in suit. The September 19 Notice Letter does not

include any non-infringement contentions unique to claims 2-20 of the '898 patent, claims 2–24 of the '131 patent, claims 2–22 of the '600 patent, claims 2-20 of the '930 patent, claims 2-24 of the '791 patent, claims 2-20 of the '975 patent, claims 2-21 of the '525 patent, claims 2-21 of the '278 patent, claims 2-27 of the '042 patent, or claims 2-6 of the '960 patent.

36. The September 19 Notice Letter does not include any detailed statement of the factual and legal basis for Defendant's opinion that the patents in suit are unenforceable.

37. The September 19 Notice Letter contends that the patents in suit are invalid as anticipated and/or obvious. The September Notice Letter does not contend that the patents in suit are invalid for lack of enablement and/or written description.

38. The September 19 Notice Letter does not include any description of the composition, formulation, ingredients, development, manufacture, or testing of the Ajanta Products beyond a vague and unsupported statement that the Ajanta Products do not contain a "release promoting agent comprising a polymer having pH-dependent solubility" or at least one "release promoting agent comprising an enteric polymer" required by certain claims of the patent in suit. Plaintiff and Defendant did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, Defendant has not produced the Ajanta ANDA to Plaintiff.

FIRST COUNT
(Defendant's Infringement of the '898 Patent)

39. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

40. Upon information and belief, Defendant seeks FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Ajanta Products.

41. Upon information and belief, Defendant included a paragraph IV certification to the '898 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '898 patent.

42. Upon information and belief, Defendant will commercially manufacture, use, sell, offer for sale, and/or import the Ajanta Products upon, or in anticipation of, FDA approval.

43. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '898 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '898 patent is an act of infringement by Defendant of one or more claims of the '898 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. §271(e)(2)(A).

44. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly and/or indirectly, one or more claims of the '898 patent under 35 U.S.C. § 271 *et seq.,* including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

45. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '898 patent under 35 U.S.C. § 271.

46. Defendant's infringement of the '898 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '898 patent.

47. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '898 patent—as well as the statutory provisions and regulations set forth in 21

U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '898 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SECOND COUNT
(Defendant's Infringement of the '131 Patent)

48. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

49. Upon information and belief, Defendant included a paragraph IV certification to the '131 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '131 patent.

50. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '131 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '131 patent is an act of infringement by Defendant of one or more claims of the '131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. §271(e)(2)(A).

51. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

52. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '131 patent under 35 U.S.C. § 271.

53. Defendant's infringement of the '131 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '131 patent.

54. As of the date of the September 20 Notice Letter, Defendant was aware of the existence of the '131 patent—as well as the statutory provisions and regulations set forth in 21U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '131 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD COUNT
(Defendant's Infringement of the '600 Patent)

55. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

56. Upon information and belief, Defendant included a paragraph IV certification to the '600 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '600 patent.

57. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '600 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '600 patent is an act of infringement by Defendant of one or more claims of the '600 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. §271(e)(2)(A).

58. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '600 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

59. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '600 patent under 35 U.S.C. § 271.

60. Defendant's infringement of the '600 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '600 patent.

61. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '600 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '600 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

FOURTH COUNT
(Defendant's Infringement of the '930 Patent)

62. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

63. Upon information and belief, Defendant included a paragraph IV certification to the '930 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '930 patent.

64. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '930 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '930 patent is an act of infringement by Defendant of one or more claims of the '930 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

65. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '930 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

66. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '930 patent under 35 U.S.C. § 271.

67. Defendant's infringement of the '930 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '930 patent.

68. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '930 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '930 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

FIFTH COUNT
(Defendant's Infringement of the '791 Patent)

69. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

70. Upon information and belief, Defendant included a paragraph IV certification to the '791 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '791 patent.

71. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '791 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '791 patent is an act of infringement by Defendant of one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

72. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

73. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '791 patent under 35 U.S.C. § 271.

74. Defendant's infringement of the '791 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '791 patent.

75. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '791 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '791 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SIXTH COUNT
(Defendant's Infringement of the '975 Patent)

76. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

77. Upon information and belief, Defendant included a paragraph IV certification to the '975 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '975 patent.

78. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '975 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '975 patent is an act of infringement by Defendant of one or more claims of the '975 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

79. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '975 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

80. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '975 patent under 35 U.S.C. § 271.

81. Defendant's infringement of the '975 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '975 patent.

82. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '975 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '975 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SEVENTH COUNT
(Defendant's Infringement of the '525 Patent)

83. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

84. Upon information and belief, Defendant included a paragraph IV certification to the '525 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '525 patent.

85. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '525 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '525 patent is an act of infringement by Defendant of one or more claims of the '525 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

86. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '525 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

87. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '525 patent under 35 U.S.C. § 271.

88. Defendant's infringement of the '525 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '525 patent.

89. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '525 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '525 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

EIGHTH COUNT
(Defendant's Infringement of the '278 Patent)

90. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

91. Upon information and belief, Defendant included a paragraph IV certification to the '278 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '278 patent.

92. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '278 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '278 patent is an act of infringement by Defendant of one or more claims of the '278 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

93. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will

infringe, directly or indirectly, one or more claims of the '278 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

94. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '278 patent under 35 U.S.C. § 271.

95. Defendant's infringement of the '278 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '278 patent.

96. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '278 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '278 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

NINTH COUNT
(Defendant's Infringement of the '042 Patent)

97. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

98. Upon information and belief, Defendant included a paragraph IV certification to the '042 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '042 patent.

99. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '042 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the

expiration of the '042 patent is an act of infringement by Defendant of one or more claims of the '042 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

100. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '042 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

101. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '042 patent under 35 U.S.C. § 271.

102. Defendant's infringement of the '042 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '042 patent.

103. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '042 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not be liable for infringement of the '042 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

TENTH COUNT
(Defendant's Infringement of the '960 Patent)

104. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

105. Upon information and belief, Defendant included a paragraph IV certification to the '960 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Ajanta Products before the expiration of the '960 patent.

106. The submission and filing of ANDA No. 217659 with a paragraph IV certification to the '960 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products before the expiration of the '960 patent is an act of infringement by Defendant of one or more claims of the '960 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

107. Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products that are the subject of ANDA No. 217659 will infringe, directly or indirectly, one or more claims of the '960 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

108. Upon information and belief, Defendant's offering for sale and/or sale of the Ajanta Products will induce and/or contribute to third-party infringement of one or more claims of the '960 patent under 35 U.S.C. § 271.

109. Defendant's infringement of the '960 patent has caused and will cause Supernus to suffer irreparable harm. Defendant's infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendant from infringing the '960 patent.

110. As of the date of the September 19 Notice Letter, Defendant was aware of the existence of the '960 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it

would not be liable for infringement of the '960 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

i. A Judgment declaring that each of the patents in suit are valid and enforceable;

ii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to FDA and filing of ANDA No. 217659 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products was an act of infringement of the patents in suit by Defendant;

iii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Ajanta Products prior to the expiration of the patents in suit, including any regulatory extensions, will constitute acts of infringement by Defendant;

iv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Ajanta Products shall be no earlier than the latest date on which an infringed patent in suit expires, including any regulatory extensions;

v. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendant and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 217659 until the latest date on which an infringed patent in suit expires, including any regulatory extensions;

vi. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendant commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 217659 that infringes any of the patents in suit;

vii. A Judgment declaring that infringement of the patents in suit is willful if Defendant commercially manufactures, uses, sells, offers to sell, and/or imports any product that is the subject of ANDA No. 217659 that infringes any of the patents in suit;

viii. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Supernus its attorneys' fees and costs; and

ix. Such other and further relief as this Court may deem just and proper.

Dated: October 28, 2022

Respectfully submitted,

By: /s/ Francis DiGiovanni

Francis DiGiovanni (#3189)
Thatcher A. Rahmeier (#5222)
222 Delaware Ave., Ste. 1410
FAEGRE DRINKER BIDDLE & REATH LLP
Wilmington, DE 19801
(302) 467-4200
francis.digiovanni@faegredrinker.com
thatcher.rahmeier@faegredrinker.com

OF COUNSEL:

Edgar H. Haug
Nicholas F. Giove
Jason A. Kanter
HAUG PARTNERS LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0888
ehaug@haugpartners.com
ngiove@haugpartners.com
jkanter@haugpartners.com

Attorneys for Plaintiff
Supernus Pharmaceuticals, Inc.